

"Pharmaceutical quality control: tips, tools & tactics"

Seminar in Berlin, Thursday, May 16, 2019
Visit to LGC GmbH, Luckenwalde, Friday, May 17, 2019
(Return to Berlin and end of event around 14.30)

Venues: Mercure Hotel Berlin City, Invalidenstraße 38, 10115 Berlin, Germany
LGC GmbH, Im Biotechnologiepark, 14943 Luckenwalde, Germany

AGENDA MAY 16, 2019

09.15–09.45 Registration

09.45–09.55 Welcome address, introduction

09.55–10.30

Reference standards in pharmaceutical analysis

Dr Christian Zeine, Global Product Manager Pharma, LGC

To set the scene for the day, this presentation gives a quick overview of the field of reference materials in pharmaceutical analysis. Primary and secondary reference standards will be introduced, as will impurity reference standards. The specific role of pharmacopoeial reference standards will be described. This overview will act as an introduction and provide the background for the rest of the day.

10.30–11.15

Elemental impurities: Multi-element analysis to ICH Q3D and USP chapters <232/233> Kirsty Macintyre, Senior Scientist, Drug Development Services, LGC

With the recent finalising of the ICH Q3D Guideline limits and the revised implementation dates for both these and USP General Chapters <232> and <233>, there is a growing need for robust and reliable analytical methodologies for elemental impurities in a wide range of pharmaceutical materials including APIs, excipients and final products. LGC has developed two approaches based on ICP-MS, utilising either a full suite limit test based screen, or a targeted, fully quantitative test for elemental impurities identified during risk assessment of the individual products. This presentation will outline the regulatory context of the guidelines, describe the analytical challenges associated with this type of testing, and highlight the key essentials in delivering multi-element quantitative data.

11.15–11.35 Coffee break

11.35–12.20

The quality of LGC's pharmaceutical reference substances

Dr. Sibylla Hoeltge, Head of Analytical Services, LGC

There are several kinds of reference materials for different requirements available on the market. In order to meet these requirements, LGC Luckenwalde is always committed to ensure the highest possible analytical quality for each product. This is realised by a variety of sometimes quite complex analytical procedures. Accuracy and reproducibility of the resulting data is regularly checked internally and externally (e.g. Proficiency Testing Studies). Furthermore, the analytical product safety is constantly enhanced by continuous improvement processes for all new and long-term established procedures. All data required for product characterization, cross checked by several parties, is provided in a comprehensive certificate. The quality of the standards is not derived from the result of an individual analysis technique, but rather from the correct combination and interpretation of a range of various results.

12.20–13.05

Supporting the industry by identifying unknown impurities: case studies

Dr Hannes Helmboldt, Head of Synthesis Group IV, LGC

Based on recent case studies from our laboratories this lecture points out how LGC can support customers in the identification of unknown impurities. LGC in Luckenwalde combines the experience of producing over 5,000 catalogue standards with the relevant equipment required for isolating and handling very small quantities of minor impurities. So if there is an unknown HPLC peak in your API or finished dosage form, contacting LGC can be the right choice to avoid much bigger problems further down the line.

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13.05–14.15 **Lunch break**

14.15–15.00

Practical aspects of method validation for impurity determination

Dr Xaver Schrott, Team Leader, GBA GROUP PHARMA

The focus of this lecture will be on the practical aspects of method validation of impurity methods in a pharmaceutical contract laboratory. The presentation covers pitfalls in setting acceptance criteria and setup of practical experiments. Real problems which occurred during more than 10 years of method validation will be presented and discussed. Another topic will be the use of relative response factors and orthogonal analytical techniques like NMR for handling complex challenges.

15.00–15.45

NDMA, NDEA & Co. in sartans – a look back and ahead

Prof. Dr. Mona Tawab, Deputy Scientific Head, German Pharmacists' Central Laboratory

No other scandal had such an impact on the pharmaceutical industry like the accidental detection of carcinogenic nitrosamines in various sartan finished products, sold to the patients over years. Starting with the detection of large amounts of N-nitrosodimethylamine (NDMA) in the µg range per tablet in valsartan finished products, the scandal is continuously widening day by day including further nitrosamines like N-nitrosodiethylamine NDEA and N-nitrosodiisopropylamine (NDiPA) in other sartan products like irbesartan and losartan. This presentation provides an insight into the root causes of this contamination, discloses the degree of contamination in various finished products and offers a look forward to the analytical requirements recommended by the authorities and those actually needed.

15.45–16.05 **Coffee break**

16.05–16.50

Proficiency Testing in analytical quality assurance: the LGC PHARMASURE scheme

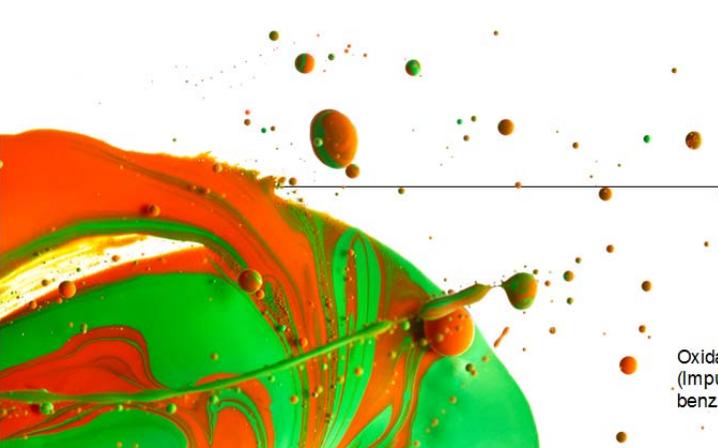
Dr. Matthew Whetton, Head of Chemistry PT, LGC PT

Proficiency Testing (PT) is defined as the evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons and as such is a key tool in the establishment and maintenance of laboratory quality. The Pharmassure PT scheme is an ISO EN 17043 accredited scheme, provided by LGC Standards in order to evaluate the performance of participant laboratories in common pharmaceutical analyses, covering routinely performed chemical and microbiological tests.

Using examples taken from the production of test materials and the data obtained from Pharmassure PT samples, we will discuss the interpretation of PT scheme performance, some of the causes of unsatisfactory performance and how PT may be used to evaluate performance over time. Aspects of various sample types will be discussed including materials provided for the determination of tablet dissolution, trace element concentration, melting point determination and microbiological sterility testing.

16.50 Final questions and answers, end of seminar around 17.15

18.00 Guided tour through Berlin's historic quarter "Hackescher Markt", following networking opportunities during dinner afterwards



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AGENDA MAY 17, 2019

07.30 Pick-up from Mercure Hotel, bus drive to LGC, Luckenwalde

ca. 09.00 Visit and guided tour of LGC, Luckenwalde
Production of Mikromol reference standards for impurities and APIs



At the LGC facility in Luckenwalde, more than 5,000 Mikromol reference standards for impurities and APIs are produced, certified, stored and maintained to support the pharmaceutical industry with materials of high quality and integrity for testing purposes. Additionally, the equipment and experience of the Luckenwalde staff offer opportunities for further customised services for the pharmaceutical industry. The tour will give an insight of the production of reference standards and the extensive analytical capabilities that are present at LGC's Luckenwalde site. Also, the warehouse with extensive storage and dispensing opportunities will be visited.



12.30 Lunch snack

13.00 Return by bus to Berlin

ca. 14.30 Arrival at Mercure Hotel Berlin City, end of event

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REGISTRATION

Please send this registration form by email to mikromol@lgcgroup.com or fax (+49 281 9887 119).

Participation fee: 200 €. Included are certificate of participation and seminar lecture slides, as well as lunch on May 16, coffee breaks on May 16/17, guided tour Berlin and dinner evening May 16, transport to and from Berlin/Luckenwalde.

Not included are travel and accommodation cost. A special contingent of rooms is reserved at the seminar hotel MERCURE Berlin-City, Invalidenstraße 38, D-10115 Berlin. Rooms are reserved for nights May 15/16 and May 16/17. Room per night €125.00 (incl. breakfast).

Please book your room yourself mentioning code "LGC" under

Phone: +49 30 30826-0

Fax: +49 3030826-100

Email: h5341@accor.com

Please do not send this registration form to the MERCURE Hotel, the hotel only manages your accommodation requirements.

Registration details of participant:

First Name:

Last Name:

Company/Institute:

Job position:

Address:

Postcode:

City:

Country:

Email:

Phone:

Internal Order No (if applicable):

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